



PATENT

Docket No. EPC-148

Box Patent Application

Commissioner of Patents and Trademarks

Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): Lisbeth Illum

1-00

WARNING: Patent must be applied for in the name(s) of all of the actual inventor(s). 37 CFR 1.41(a) and 1.53(b).

For (title): "Small Particle Compositions For Intranasal Drug Delivery"

1. Type of Application

This new application is for a(n) (check one applicable item below):

- ☒ Original
☐ Design
☐ Plant

WARNING: Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4) unless the International Application is being filed as a divisional, continuation or continuation-in-part application.

NOTE: If one of the following 3 items apply then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.

- ☐ Divisional
☐ Continuation
☒ Continuation-in-part (CIP)

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date May 21, 1993 in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number TB292749182US addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Anna-Louise Owens

(Type or print name of person mailing paper)

Anna Louise Owens

(Signature of person mailing paper)

NOTE: Each paper or fee referred to as enclosed herein has the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 CFR 1.10(b).

2. Benefit of Prior U.S. Application(s) (35 USC 120)

NOTE: If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., then check the following item and complete and attach **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**.

- ☒ The new application being transmitted claims the benefit of prior U.S. application(s) and enclosed are **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**.

3. Papers Enclosed Which Are Required For Filing Date Under 37 CFR 1.53(b) (Regular) or 37 CFR 1.153 (Design) Application

26 Pages of specification

2 Pages of claims

1 Pages of Abstract

3 Sheets of drawing

☒ formal

☐ informal

WARNING: DO NOT submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. Comments on proposed new 37 CFR 1.84. Notice of March 9, 1988 (1990 O.G. 57-62).

NOTE: "Identifying indicia such as the serial number, group and unit, title of the invention, attorney's docket number, inventor's name, number of sheets, etc., not to exceed 2 3/4 inches (7.0 cm.) in width may be placed in a centered location between the side edges within three fourths inch (19.1 mm.) of the top edge. Either this marking technique on the front of the drawing or the placement, although not preferred, of this information and the title of the invention on the back of the drawings is acceptable." Proposed 37 CFR 1.84(1). Notice of March 9, 1988 (1090 O.G. 57-62).

4. Additional papers enclosed

- ☒ Preliminary Amendment
- ☐ Information Disclosure Statement (37 CFR 1.98)
- ☐ Form PTO-1449
- ☐ Citations
- ☐ Declaration of Biological Deposit
- ☐ Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.
- ☐ Authorization of Attorney(s) to Accept and Follow Instructions from Representative
- ☐ Special Comments
- ☐ Other

5. Declaration or oath

☐ Enclosed

executed by (check all applicable boxes)

☐ inventor(s).☐ legal representative of inventor(s). 37 CFR 1.42 or 1.43☐ joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.☐ this is the petition required by 37 CFR 1.47 and the statement required by 37 CFR 1.47 is also attached. See item 13 below for fee.☒ Not Enclosed. (*unperfected form encl.*)

WARNING: Where the filing is a completion in the U.S. of an International Application but where a declaration is not available or where the completion of the U.S. application contains subject matter in addition to the International Application the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.

☐ Application is made by a person authorized under 37 CFR 1.41(c) on behalf of all the above named inventor(s). (The declaration or oath, along with the surcharge required by 37 CFR 1.16(e) can be filed subsequently).

NOTE: It is important that all the correct inventor(s) are named for filing under 37 CFR 1.41(c) and 1.53(b).

☐ Showing that the filing is authorized. (Not required unless called into question. 37 CFR 1.41(d).)

6. Inventorship Statement

WARNING: If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.

The inventorship for all the claims in this application are:

☒ The same

or

☐ Are not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,☐ is submitted.☐ will be submitted.

7. Language

NOTE: An application including a signed oath or declaration may be filed in a language other than English. A verified English translation of the non-English language application and the processing fee of \$130.00 required by 37 CFR 1.17(k) is required to be filed with the application or within such time as may be set by the Office. 37 CFR 1.52(d).

NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 CFR 1.69(b).

☒ English☐ non-English☐ the attached translation is a verified translation. 37 CFR 1.52(d).

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8. Assignment

☒ An assignment of the invention to Danbiosyst UK Limited

☐ is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1906 is also attached.

☒ will follow.

NOTE: "If an assignment is submitted with a new application, send two separate letters—one for the application and one for the assignment." Notice of May 4, 1990 (1114 O.G. 77-78).

9. Certified Copy

Certified copy(ies) of application(s)

<u>Great Britain</u>	<u>8924935.3</u>	<u>November 4, 1989</u>
(country)	(appln. no.)	(filed)
<u>PCT/GB90/01676</u>		<u>November 1, 1990</u>
(country)	(appln. no.)	(filed)
(country)	(appln. no.)	(filed)

from which priority is claimed

☐ is(are) attached.

☐ will follow.

NOTE: The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 CFR 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. 120 is itself entitled to priority from a prior foreign application then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

10. Fee Calculation (37 CFR 1.16)

A. ☒ Regular application

CLAIMS AS FILED						
Number filed	Number Extra			Rate	Basic Fee 37 CFR 1.16(a) \$710.00	
Total						
Claims (37 CFR 1.16(c))	14	-20=	0	X	\$ 22.00	0
Independent						
Claims (37 CFR 1.16(b))	1	-3=	0	X	\$ 74.00	0
Multiple dependent claim(s), if any (37 CFR 1.16(d))					\$230.00	0

☐ Amendment cancelling extra claims enclosed.

☒ Amendment deleting multiple-dependencies enclosed.

☐ Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 CFR 1.16(d).

Filing Fee Calculation

\$ 710.00

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- B. ☐ Design application (\$280.00—37 CFR 1.16(f))

Filing Fee Calculation \$ _____

- C. ☐ Plant application (\$460.00—37 CFR 1.16(g))

Filing fee calculation \$ _____

11. Small Entity Statement(s)

- ☐ Verified Statement(s) that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is(are) attached.

Filing Fee Calculation (50% of A, B or C above) \$ _____

NOTE: Any excess of the full fee paid will be refunded if a verified statement and a refund request are filed within 2 months of the date of timely payment of a full fee. 37 CFR 1.28(a).

12. Request for International-Type Search (37 CFR 1.104(d)) (complete, if applicable)

- ☐ Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. Fee Payment Being Made At This Time

- ☐ Not Enclosed

- ☐ No filing fee is to be paid at this time. (This and the surcharge required by 37 CFR 1.16(e) can be paid subsequently.)

- ☒ Enclosed

- ☒ basic filing fee \$ 710.00

- ☐ recording assignment (\$40.00; 37 CFR 1.21(h)) \$ _____

- ☐ petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached. (\$130.00; 37 CFR 1.47 and 1.17(h)) \$ _____

- ☐ for processing an application with a specification in a non-English language. (\$130.00; 37 CFR 1.52(d) and 1.17(k)) \$ _____

- ☐ processing and retention fee (\$130.00; 37 CFR 1.53(d) and 1.21(l))

- ☐ fee for international-type search report (\$35.00; 37 CFR 1.21(e)). \$ _____

NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application which is abandoned for failing to complete the application pursuant to 37 CFR 1.53(d) and this, as well as the changes to 37 CFR 1.53 and 1.78, indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid or the processing and retention fee of § 1.21(l) must be paid within 1 year from notification under § 53(d).

Total fees enclosed \$ 710.00

14. Method of Payment of Fees

- ☒ Check in the amount of \$ 710.00
- ☐ Charge Account No. _____ in the amount of \$ _____. A duplicate of this transmittal is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).

15. Authorization to Charge Additional Fees

WARNING: If no fees are to be paid on filing the following items should **not** be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

- ☒ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. 12-2147.

☒ 37 CFR 1.16(a), (f) or (g) (filing fees)

☒ 37 CFR 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

☒ 37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

☒ 37 CFR 1.17 (application processing fees)

WARNING: While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a) this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 C.F.R. 1.136(a) is to no avail unless a request or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27).

☐ 37 CFR 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 CFR 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b).

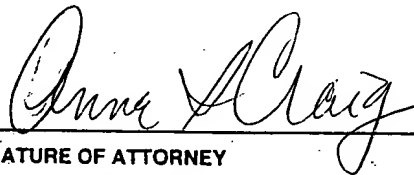
NOTE: 37 CFR 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . . issue fee". From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

16. Instructions As To Overpayment

- ☒ credit Account No. 12-2147
- ☐ refund

Reg. No. 32,976

Tel. No. (617) 227-0700



SIGNATURE OF ATTORNEY

Anne I. Craig

Type or print name of attorney

Lorusso & Loud

P.O. Address

440 Commercial St. Boston, MA 02109

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☒ **Incorporation by reference of added pages**

Check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED

- ☒ Plus Added Pages For New Application Transmittal Where Benefit Of Prior U.S. Application(s) Claimed

Number of pages added 4

- ☒ Plus Added Pages For Papers Referred To In Item 4 Above

Number of pages added 2

- ☐ Plus "Assignment Cover Letter Accompanying New Application"

Number of pages added _____

☐ **Statement Where No Further Pages Added**

(If no further pages form a part of this Transmittal then end this Transmittal with this page and check the following item)

- ☐ This transmittal ends with this page.

**ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF
PRIOR U.S. APPLICATION(S) CLAIMED**

NOTE: "In order for an application to claim the benefit of a prior filed copending national application, the prior application must name as an inventor at least one inventor named in the later filed application and disclose the named inventor's invention claimed in at least one claim of the later filed application in the manner provided by the first paragraph of 35 U.S.C. 112." 37 CFR 1.78(a).

NOTE: "In addition the prior application must be (1) complete as set forth in § 1.51, or (2) entitled to a filing date as set forth in § 1.53(b) and include the basic filing fee set forth in § 1.16; or (3) entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(l) within the time period set forth in § 1.53(d)." 37 CFR 1.78(a).

17. Relate Back—35 U.S.C. 120

NOTE: "Any application claiming the benefit of a prior filed copending national or international application must contain or be amended to contain in the first sentence of the specification following the title a reference to such prior application identifying it by serial number and filing date or international application number and international filing date and indicating the relationship of the applications." 37 CFR 1.78(a). See also the Notice of April 28, 1987 (1079 O.G. 32 to 46).

☒ Amend the Specification by inserting before the first line the sentence:

"This is a

- ☐ continuation
☒ continuation-in-part
☐ divisional

of copending application(s)

- ☒ serial number 0 7/ 842,351 filed on March 24, 1992 "nwabw.)
☒ International Application PCT/GB90/01676 filed on November 1, 1990 and which designated the U.S." 5/27

NOTE: The proper reference to a prior filed PCT application which entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application which designated the U.S.

NOTE: (1) Where the application being transmitted adds subject matter to the International Application then the filing can be as a continuation-in-part or (2) it is desired to do so for other reasons, e.g. where no declaration is available, no English translation is available or no fee is to be paid on filing then the filing can be as a continuation. In these cases the International Application designating the U.S. is treated as the parent case in the U.S. and is an alternative to the completion of the International Application under 35 U.S.C. 371(c)(4) which must meet the requirements of 37 CFR 1.61(a). This alternative permits the completion of the filing requirements within any term set by the PTO under 37 CFR 1.53(d) to which the extension provisions of 37 CFR 1.136(a) apply. (Whereas, if the filing is as an international application entering the U.S. stage then the fee, declaration and/or English translation (where necessary) is due within 20 months of the priority date but can be paid within 22 months of the priority date (or is due within 30 months of the priority date but can be submitted within 32 months of the priority date) with the surcharges set forth in 37 CFR 1.492(e), (f) and 37 CFR 1.495(c); however, the provisions of 37 CFR 1.136 do not apply to this 22 or (32 month) period. 37 CFR 1.61(b).)

NOTE: The deadline for entering the national phase in the U.S. for an international application was clarified in the Notice of April 28, 1987 (1079 O.G. 32 to 46) as follows:

"The Patent and Trademark Office considers the International application to be pending until the 22nd month from the priority date if the United States has been designated and no Demand for International Preliminary Examination has been filed prior to the expiration of the 19th month from the priority date and until the 32nd month from the priority date if a Demand for International Preliminary Examination which elected the United States of America has been filed prior to the expiration of the 19th month from the priority date, provided that a copy of the international application has been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively. If a copy of the international application has not been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively, the international application becomes abandoned as to the United States 20

or 30 months from the priority date respectively. These periods have been placed in the rules as paragraph (h) of § 1.494 and paragraph (i) of § 1.495. A continuing application under 35 U.S.C. 365(c) and 120 may be filed anytime during the pendency of the international application."

18. Relate Back—35 U.S.C. 119 Priority Claim for Prior Application

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 17, in turn itself claim(s) foreign priority (ies) as follows:

Great Britian	8924935.3	November 4, 1989
country	appl. no.	filed on

The certified copy (ies) has (have)

- ☒ been filed on _____ in prior application 0 7/ 842,351 which was filed on March 24, 1992 by International Bureau
- ☐ is (are) attached

WARNING: The certified copy of the priority application which may have been communicated to the PTO by the International Bureau may **not** be relied on without any need to file a certified copy of the priority application in the continuing application. This is so because the certified copy of the priority application communicated by the International Bureau is placed in a folder and is not assigned a U.S. serial number unless the national stage is entered. Such folders are disposed of if the national stage is not entered. Therefore such certified copies may not be available if needed later in the prosecution of a continuing application. An alternative would be to physically remove the priority documents from the folders and transfer them to the continuing application. The resources required to request transfer, retrieve the folders, make suitable record notations, transfer the certified copies, enter and make a record of such copies in the Continuing Application are substantial. Accordingly, the priority documents in folders of international applications which have not entered the national stage may not be relied on. Notice of April 28, 1987 (1079 O.G. 32 to 46).

19. Maintenance of Coadependency of Prior Application

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).

- A. ☐ Extension of time in prior application

(This item **must** be completed and the papers filed in the **prior application** if the period set in the prior application has run)

- ☐ A petition, fee and response extends the term in the pending prior application until _____
- ☐ A copy of the petition filed in prior application is attached

- B. ☐ Conditional Petition for Extension of Time in Prior Application

(complete this item if previous item not applicable)

- ☐ A conditional petition for extension of time is being filed in the pending prior application.
- ☐ A copy of the conditional petition filed in the prior application is attached

20. Further Inventorship Statement Where Benefit of Prior Application(s) Claimed

NOTE: "If the continuation, continuation-in-part, or divisional application is filed by less than all the inventors named in the prior application a statement must accompany the application when filed requesting deletion of the names of the person or persons who are not inventors of the invention being claimed in the continuation, continuation-in-part, or divisional application." 37 CFR 1.62(a) [emphasis added]. (dealing with the file wrapper continuation situation).

NOTE: "In the case of a continuation-in-part application which adds and claims additional disclosure by amendment, an oath or declaration as required by § 1.63 must be filed. In those situations where a new oath or declaration is required due to additional subject matter being claimed, additional inventors may be named in the continuing application. In a continuation or divisional application which discloses

and claims only subject matter disclosed in a prior application, no additional oath or declaration is required and the application must name as inventors the same or less than all the inventors in the prior application." 37 CFR 1.60(c). (dealing with the continuation situation).

(complete applicable item (a), (b) and/or (c) below)

- (a) ☐ This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) in this application are
- ☐ the same
 - ☐ less than those named in the prior application and it is requested that the following inventor(s) identified for the prior application be deleted:

(Type name(s) of inventor(s) to be deleted)

- (b) ☒ This application discloses and claims additional disclosures by amendment and a new declaration or oath is being filed. With respect to the prior application the inventor(s) in this application are
- ☒ the same
 - ☐ the following additional inventor(s) have been added

(Type name(s) of inventor(s) to be added)

- (c) The inventorship for all the claims in this application are
- ☒ the same
 - ☐ not the same, and an explanation, including the ownership of the various claims at the time the last claimed invention was made
 - ☐ is submitted
 - ☐ will be submitted

21. Abandonment of Prior Application (if applicable)

- ☒ Please abandon the prior application at a time while the prior application is pending or when the petition for extension of time or to revive in that application is granted and when this application is granted a filing date so as to make this application copending with said prior application.

NOTE: According to the Notice of May 13, 1983 (103, TMOG 6-7) the filing of a continuation or continuation-in-part application is a proper response with respect to a petition for extension of time or a petition to revive and should include the express abandonment of the prior application conditioned upon the granting of the petition and the granting of a filing date to the continuing application.

22. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

WARNING: "The claims of a new application may be finally rejected in the first Office action in those situations where (1) the new application is a continuing application of, or a substitute for, an earlier application, and (2) all the claims of the new application (a) are drawn to the same invention claimed in the earlier application, and (b) would have been properly finally rejected on the grounds of art of record in the next Office action if they had been entered in the earlier application." MPEP, § 706.07(b).

NOTE: Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary.

(Added Pages for Application Transmittal Where Benefit of Prior U.S. Application(s)
Claimed [4-1.1]—page 3 of 4)

(check the next item, if applicable)

- ☐ There is provided herewith a Petition To Suspend Prosecution for the Time Necessary to File An Amendment (New Application Filed Concurrently)

23. NOTIFICATION IN PARENT APPLICATION OF THIS FILING

- ☒ A notification of the filing of this
(check one of the following)

- ☐ continuation
☒ continuation-in-part
☐ divisional

will be
is being filed in the parent application from which this application claims priority under 35 USC § 120.